

**REMARKS / ARGUMENTS**

**1. Dayco / McKesson Disclosure**

In accordance the undersigned's current understanding of the obligations imposed by *Dayco Products, Inc. v. Total Containment, Inc.*, 329 F.3d 1358 (Fed. Cir. 2003) and *McKesson Information Solutions, Inc. v. Bridge Medical, Inc.*, 487 F.3d 897 (Fed. Cir. 2007), the following co-pending application(s) whose file history may contain material information are identified. In assessing the patentability of the pending claims, the Office is respectfully requested to review the file history of each the listed co-pending application(s), determine whether such co-pending application has "similar subject matter" and, if so, consider each Office Action, including each reference on which a rejection is based, and each paper submitted by applicant therein.

- a. The subject matter of this application may be related to the subject matter of application serial no. 10/501,112, which is currently pending before Examiner Evanisco. This application is currently on Appeal.
- b. The subject matter of this application may be related to the subject matter of application serial no. 11/663,115, which has not yet been assigned to an Examiner.
- c. The subject matter of this application may be related to the subject matter of application serial no. 12/134,084, which has not yet been assigned to an Examiner.

**2. Response to 02/25/2010 Non-Final Office Action**

For the convenience of the Examiner and clarity of purpose, Assignee has reprinted the substance of the Office Action in *9-point bolded and italicized font*. Assignee's arguments immediately follow in regular font.

*Claims 1,6,8,10-12,16, and 17 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claimed invention is directed to a judicial exception to 35 U.S.C. 101 (an abstract idea) and is not directed to a practical application of such judicial exception because the claim does not require any physical transformation and the invention as claimed does not produce a useful, concrete, and tangible result.*

Assignee traverses this ground of rejection. First, the currently pending claims are tied to a particular machine, and are therefore not required to separately involve any physical transformation. See *In re Bilski*, 545 F.3d 943, 954 (Fed. Cir. 2008) (“A claimed process is surely patent-eligible under § 101 if: (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing.”).

In the instant case, claim 1 recites “[a] method of controlling a blood pump, comprising: analyzing an instantaneous flow waveform in both the time domain and frequency domain; and controlling the pump in response thereto”. Thus, the method steps of claim 1 are tied to a blood pump, and therefore meet the so-called “machine or transformation” test of *In Re Bilski*.

Furthermore, the controlling step is not merely insignificant post solution activity, under *In Re Bilski*, because the entire point of claim 1 is to control the blood pump. Thus, the controlling step is crucial. Furthermore, the Board of Patent Appeals and Interferences recently held that “a computerized method which includes a step of outputting information from a computer [is] tied to a particular machine or apparatus”. *Ex Parte Dickerson*, Appeal 2009-001172 (BPAI 2009). If merely outputting information from a computer is sufficiently tied to a particular machine or apparatus, as held by the BPAI in *Ex Parte Dickerson*, actually controlling a blood pump, as claimed in claim 1, must surely be sufficiently tied to a particular machine or apparatus as well.

Second, controlling the blood pump, as claimed in claim 1, is a practical application. For example, Assignee assures the Examiner that anyone depending on Assignee’s blood pumps would certainly agree that controlling the blood pump, as claimed in claim 1, produces a useful, concrete, and tangible result, such as maintaining a proper rate of blood flow through their bodies, thereby keeping them alive. Of course, *In Re Bilski*’s so-called “machine or transformation” test effectively replaces the “useful, concrete and tangible result” test of State

Street. *In re Bilski*, 545 F.3d 943 ("those portions of our opinions in State Street and AT&T relying solely on a "useful, concrete and tangible result" analysis should no longer be relied on"). Therefore, claim 1 and those claims depending therefrom are directed to statutory subject matter. Reconsideration and withdrawal of this rejection is requested.

*Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.*

*Claim 16 recites the limitation "the Constant Speed mode" in line 2. There is insufficient antecedent basis for this limitation in the claim.*

Claim 16 has been amended to obviate this ground of rejection.

*Claims 1, 6, 8, 10-12, 16, and 17 rejected under 35 U.S.C. 102(b) as being anticipated by Ash (US 4995268).*

*As to claim 1, Ash discloses a method of controlling a blood pump, comprising: analyzing an instantaneous flow waveform in both the time domain and frequency domain; and controlling the pump in response thereto (col. 12 ll. 5-70).*

As an initial matter, Assignee does not accede to the Office's characterization of Ash as applied to the claims and Assignee respectfully reserves its right to present additional challenges that characterization in the future.

Claim 1 recites "analyzing an instantaneous flow waveform in ***both the time domain and frequency domain***", emphasis added.

In contrast, Ash does not disclose analyzing any waveform in the frequency domain, much less "analyzing an instantaneous flow waveform in *both* the time domain *and* frequency domain", as claimed. In fact, Ash does not even mention the word "waveform". While Ash does claim "displaying a frequency for said pulsating blood flow", in claim 15, that is his only use of the word "frequency". One with ordinary skill in the art would understand that the frequency of a

pulsating blood flow would be related to the patient's heart rate, as the heart is the source of such pulsatility. Thus, this sole use of the word "frequency" is directed to merely displaying the patient's heart rate, or something akin thereto. There is absolutely no discussion of performing any analysis of this frequency.

For at least these reasons, Assignee respectfully submits that claim 1 is patentable over the disclosure and teaching of Ash. Reconsideration and withdrawal of this rejection is requested.

***As to claim 6, Ash discloses the method of claim 1, in which the analysis of the flow wave form determines a suction boundary condition (col. 12 ll. 5-70).***

Claim 6 recites "in which the analysis of the flow wave form determines a suction boundary condition".

In contrast, Ash does not even include the word "suction" much less "determines a suction boundary condition", as claimed. For at least this reason, Assignee respectfully submits that claim 6 is patentable over the disclosure and teaching of Ash. Reconsideration and withdrawal of this rejection is requested.

***As to claim 8, Ash discloses the method of claim 6, further comprising boundary conditions for maximum power, maximum speed, minimum speed, minimum flow, change in flow peak-to-peak amplitude over change in pump speed, change in mean flow over change in pump's speed, and change in pump power over change in pump speed (col. 12 ll. 5-70).***

Claim 8 recites "further comprising boundary conditions for maximum power, maximum speed, minimum speed, minimum flow, change in flow peak-to-peak amplitude over change in pump speed, change in mean flow over change in pump speed, **and** change in pump power over change in pump speed", emphasis added.

In contrast, Ash appear completely devoid of any mention of several of these boundary conditions. For example, while Ash does calculate an **average** flow rate, such an average is not a **mean** flow, much less in any way indicative of "**change** in mean flow over **change** in pump speed", emphasis added, as claimed. Assignee can find nothing even remotely related to "change in flow peak-to-peak amplitude over change in pump speed", "change in pump power over change in pump speed", or others of the claim limitations. For at least these reasons, Assignee respectfully submits that claim 8 is patentable over the disclosure and teaching of Ash. Reconsideration and withdrawal of this rejection is requested.

*As to claim 10, Ash discloses the method of claim 6 or claim 8 where the boundary conditions become control parameters for closed loop control (col. 12 ll. 5-70).  
As to claim 11, Ash discloses the method of claim 6 or claim 8 where the boundary conditions cause the control system to clamp pump speed, and where upper boundary conditions do not allow the speed to be increased further while lower boundary conditions do not allow the speed to be decreased further (col. 12 ll. 5-70).  
As to claim 12, Ash discloses the method of claim 6 or claim 8 where the boundary condition of suction causes a predetermined decrease in speed then periodically attempts to return to the desired control mode at predetermined intervals (col. 12 ll. 5-70).*

Because Ash does not disclose the limitations of claims 6 or 8, Ash cannot possibly anticipate the limitations of claims 10-12. For at least this reason, Assignee respectfully submits that claims 10-12 are patentable over the disclosure and teaching of Ash. Reconsideration and withdrawal of this rejection is requested.

*As to claim 16, Ash discloses the method of claim 1 where a fail-safe feature to switch to the Constant Speed mode is automatically enabled in the event of a lost, erroneous, or compromised flow signal (col. 10 ll. 10-20).*

Claim 16 now recites "where a fail-safe feature to switch to a Constant Speed mode is automatically enabled in the event of a lost, erroneous, or compromised flow signal".

In contrast, Assignee can find no teaching of any such fail-safe feature in Ash. For at

least this reason, Assignee respectfully submits that claim 16 is patentable over the disclosure and teaching of Ash. Reconsideration and withdrawal of this rejection is requested.

*As to claim 17, Ash discloses the method of claim 1 where the quality of the flow signal is determined by the frequency domain analysis of the real-time flow waveform (col. 12 ll.5-70).*

Claim 17 recites “where the quality of the flow signal is determined by the frequency domain analysis of the real-time flow waveform”.

In contrast, as discussed above, Ash does not disclose analyzing any waveform in the frequency domain, much less “where the quality of the flow signal is determined by the frequency domain analysis of the real-time flow waveform”, as claimed. In fact, Ash does not even mention the word “waveform”, the word “quality”, or the term “frequency domain”. Therefore, there is absolutely no discussion of signal quality, much less “where the quality of the flow signal is determined by the frequency domain analysis of the real-time flow waveform”, as claimed.

For at least these reasons, Assignee respectfully submits that claim 17 is patentable over the disclosure and teaching of Ash. Reconsideration and withdrawal of this rejection is requested.

**3. New Claims 20 - 31**

New claims 20 – 31 are presented herein to more particularly point and distinctly claim certain aspects of the disclosed inventions.

**4. Conclusion**

In responding to this Office Action, Assignee has presented only those arguments and

made only those amendments that Assignee believes are warranted. Assignee has not, for example, responded to every factual or legal issue raised by the Office, and Assignee has not presented every argument supporting patentability that may be relevant. The decision not to address a factual or legal issue raised or to present a certain argument in support shall not be construed as Assignee's agreement with the Office on such issue or effect a waiver of Assignee's right to address such issues or make such arguments in the future.

Claims 1, 6, 8, 10-12, 16, 17, and 20-31 are currently pending in this application, with claims 1, 6, 8, 10-12, 16, and 17 being rejected.

Claim 16 has been amended herein and Assignee submits that each claim presented herein is patentable. A timely notice of allowance is respectfully requested.

Assignee thanks the Examiner for his/her consideration and effort on this file. If there are any questions or if additional information is needed, the Examiner is invited to telephone or email the undersigned.

Respectfully submitted,

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